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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 743,163	01 18 2001	Brian J. Nickoloff	ISPH-0531	6074

262-9 7590 03 26 2002

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EXAMINER

DECLoux, Amy M

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 03 26 2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/743,163

Applicant(s)

NICKOLOFF, BRIAN J.

Examiner

Amy M. DeCloux

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-19 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-3, drawn to a method of inhibiting a NK-T cell-mediated immunological reaction comprising the step of contacting a cell with a composition reactive with a MHC class I or MHC Class I-like molecule that inhibits an interaction between a MHC Class I or MHC Class I-like molecule and a receptor on the NK-T cell where the receptor is selected from the group consisting of CD158a, CD158b, and CD161.

Group II, claim(s) 4-5, drawn to a method of treating a cutaneous or extracutaneous disorder comprising administering a composition that inhibits an interaction between a MHC Class I or MHC Class I-like molecule and a receptor on the NK-T cell.

Group III, claim(s) 6-10, drawn to a method of diagnosing psoriasis or susceptibility to psoriasis in a patient comprising detecting a mutation in a novel ligand/receptor.

Group IV, claim(s) 11-18, drawn to a method of treating a disorder of the skin comprising administering a composition that activates NK-T cell receptors or components of a cell signaling pathway associated with NK-T cell receptors.

Group V, claim(s) 19, drawn to a method for treating a skin disorder comprising administering a composition that alters the expression of novel receptors/ligands.

2. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Mandelboin et al (1997)(PNAS 94:14666-14670) teach a method of inhibiting a NK-T cell-mediated immunological reaction comprising the step of contacting a cell with class I specific monoclonal antibodies that inhibits the interaction between a MHC class I or MHC

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Class I-like molecule and CD158a and CD158b (NKIR1 and NKIR2, respectively) receptor on the NK-T cell .

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

4. The species are as follows:

In Group I,

- A) a method comprising a **specific receptor**, such as CD158a as recited in claim 1,
- B) a method comprising a **specific Class I molecule**, such as CD1d as recited in claim 3,
- C) a method comprising a **specific antibody**,

In Group II,

- A) a method comprising a **specific receptor**, such as CD158a as recited in claim 1,
- B) a method comprising a **specific Class I molecule**, such as CD1d as recited in claim 3,
- C)) a method comprising a **specific disorder** such as one recited in claim 5,

In Group III,

- A) a method comprising a **specific mutation**,
- B) a method comprising a **specific novel receptor/ligand**,

In Group IV,

- A) a method comprising a **specific disorder** such as one recited in claim 5,
- B) a method comprising a **specific composition** with a **specific active ingredient(s)**, such as an antibody directed to a **specific NK-T receptor**,
- C) a method comprising a **specific signaling pathway**,

In Group V,

- A) a method comprising a **specific disorder** such as one recited in claim 5,
- B) a method comprising a **specific composition** with a **specific active ingredient(s)**, such as an antibody directed to a **specific NK-T receptor**,
- C) a **specific novel receptor/ligand**,

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5. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

6. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

7. The following claim(s) are generic: Claims 1-19 in at least one aspect.

8. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

Specific Class I molecules differ with respect to their amino acid sequence and structural and functional properties,

Specific antibodies differ with respect to their amino acid sequence and structural and functional properties,

Specific receptors differ with respect to their amino acid sequence and structural and functional properties,

Specific mutations differ with respect to the amino acid sequence and structural and functional properties conferred by said mutation,

Specific receptor /ligands differ with respect to their amino acid sequence and structural and functional properties,

Specific disorders differ in their etiology and their symptoms,

Specific signaling pathways differ with respect to the the components of the pathways and to the effect of the pathways.

9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. a message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to

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the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot Program. If you have any questions or suggestions, please contact Paula Hutzell, Supervisory Patent Examiner at paula.hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers **(other than elections)** should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.
Patent Examiner
Group 1640, Technology Center 1600
March 25, 2002

Amy DeCloux 3/25/02